

## **EXHIBIT 1**

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## UNITED STATES DISTRICT COURT

for the

Western District of Washington

TODD AND ANNE ERICKSON,

*Plaintiff*

v.

MICROAIRE SURGICAL INSTRUMENTS, LLC

*Defendant*

Civil Action No. 3:08-CV-05745-FDB

(If the action is pending in another district, state where:

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS  
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Jennifer Forshey, DMD, MD, c/o Stephen Teller, 1139 34th Avenue, Suite B, Seattle, WA 98122

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: See Schedule A attached hereto.

Place: Ogden Murphy Wallace, PLLC (ATTN: Jaime Allen) 1601 5th Avenue, Suite 2100 Seattle, WA 98101	Date and Time:  04/14/2010 9:00 am
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☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:
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The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 03/31/2010

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party) Microaire Surgical Instruments, LLC, who issues or requests this subpoena, are:

Jaime Drozd Allen, Ogden Murphy Wallace, PLLC, 1601 5th Avenue, Suite 2100, Seattle, WA 98101,  
jallen@omwlaw.com, (206) 447-7000.

Civil Action No. 3:08-CV-05745-FDB

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*

This subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named person as follows: \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_  
\_\_\_\_\_.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

**Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)****(c) Protecting a Person Subject to a Subpoena.**

**(1) Avoiding Undue Burden or Expense; Sanctions.** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

**(2) Command to Produce Materials or Permit Inspection.**

**(A) Appearance Not Required.** A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

**(B) Objections.** A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

**(i)** At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

**(ii)** These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

**(3) Quashing or Modifying a Subpoena.**

**(A) When Required.** On timely motion, the issuing court must quash or modify a subpoena that:

**(i)** fails to allow a reasonable time to comply;

**(ii)** requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

**(iii)** requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

**(iv)** subjects a person to undue burden.

**(B) When Permitted.** To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

**(i)** disclosing a trade secret or other confidential research, development, or commercial information;

**(ii)** disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

**(iii)** a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

**(C) Specifying Conditions as an Alternative.** In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

**(i)** shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

**(ii)** ensures that the subpoenaed person will be reasonably compensated.

**(d) Duties in Responding to a Subpoena.**

**(1) Producing Documents or Electronically Stored Information.** These procedures apply to producing documents or electronically stored information:

**(A) Documents.** A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

**(B) Form for Producing Electronically Stored Information Not Specified.** If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

**(C) Electronically Stored Information Produced in Only One Form.** The person responding need not produce the same electronically stored information in more than one form.

**(D) Inaccessible Electronically Stored Information.** The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

**(2) Claiming Privilege or Protection.**

**(A) Information Withheld.** A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

**(i)** expressly make the claim; and

**(ii)** describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

**(B) Information Produced.** If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

**(e) Contempt.** The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

## SCHEDULE A

### A. Definitions

1. "Concerning" or "Concerns" includes, but is not limited to, the following meanings: relating to, referring to, pertaining to, regarding, constituting, discussing, mentioning, containing, reflecting, evidencing, referencing, involving, arising out of, in connection with, describing, displaying, showing, and identifying.

2. "Document" or "Documents" includes, but is not limited to, writings of every kind, source, and authorship, both originals and non-identical copies thereof, as well as all drafts or summaries, in whole or in part, in Your possession, custody, or control. A writing includes but is not limited to letters, words, numbers, data compilations (including field data or field notes), calculations, pictures, drawings, photographs, symbols, sounds, or combinations thereof or their equivalent, including any and all handwritten, typewritten, printed, photocopied, or recorded matter, regardless of the media used, and specifically any and all correspondence, e-mails, Electronic Media, Electronically Stored Information, transcripts of testimonies, letters, memoranda, notes, reports, papers, files, books, records, contracts, agreements, telegrams, teletypes and other communications sent or received, diaries, calendars, telephone logs, drafts, work papers, agenda, bulletins, notices, announcements, instructions, charts, maps, plans, photographs, microfilm, data processed or image processed document, information stored or maintained electronically or by sound-recording or in a similar device, manuals, brochures, schedules, summaries, notes, minutes and other records and recordings of any conferences, meetings, visits, statements, interviews, or telephone conversations, bills, statements, and other records of obligations and expenditures, cancelled checks, vouchers, receipts, and other records of payments, financial data, analysis, statements, interviews, affidavits, printed matter (including books, articles, speeches, newspaper clippings), press releases, file memoranda or other internal documents, and photographs, and all drafts and/or non-identical copies thereof.

3. "Electronically Stored Information" includes but is not limited to writings, drawings, graphs, charts, photographs, sound recordings, images and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.

4. "Electronic Media" includes, but is not limited to, all computer-generated, processed or stored information, e-mail, databases, data, word processing files, backup tapes, files, disks, hard drives and any other electronically stored information, in its native format, including all metadata.

5. "Sound Oral & Maxillofacial Surgery, P.S." means all derivations and abbreviations of Sound Oral & Maxillofacial Surgery, including but not limited to, "Sound Oral," "Dr. Robert Todd Erickson, DDS," "Sound Oral Surgery," "SOMS," "Dr. Robert Erickson," and "Sound Oral Maxillofacial."

**B. Documents to Produce**

1. Please produce all witness statements obtained in or concerning the issues in *Forshey v. SOMS, Inc. et. al.* (W.D. Wash. Case No. C06-5335-RJB). This request does not include any documents that are subject to the attorney-client privilege or work product doctrine.
2. Please produce all deposition transcripts, along with accompanying exhibits, as well as videotapes of any depositions, concerning the lawsuit captioned *Forshey v. SOMS, Inc. et. al.* (W.D. Wash. Case No. C06-5335-RJB).
3. Please produce any settlement agreements, or other contracts or agreements, between you and Todd Erickson, Anne Erickson, and/or Sound Oral & Maxillofacial Surgery.
4. Please produce any employment contracts that you have with Todd and/or Anne Erickson and/or Sound Oral & Maxillofacial Surgery, P.S.

## UNITED STATES DISTRICT COURT

for the

Western District of Washington

TODD AND ANNE ERICKSON,

*Plaintiff*

v.

MICROAIRE SURGICAL INSTRUMENTS, LLC

*Defendant*

Civil Action No. 3:08-CV-05745-FDB

(If the action is pending in another district, state where: )

## SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Jennifer Forshey, DMD, MD, c/o Stephen Teller, 1139 34th Avenue, Suite B, Seattle, WA 98122

☒ **Testimony:** YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place: Ogden Murphy Wallace, PLLC  
1601 5th Avenue, Suite 2100  
Seattle, WA 98101

Date and Time:

04/21/2010 9:00 am

The deposition will be recorded by this method: audiovisual, stenographic

☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 03/31/2010

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party) Microaire Surgical Instruments, LLC, who issues or requests this subpoena, are:  
Jaime Drozd Allen, Ogden Murphy Wallace, PLLC, 1601 5th Avenue, Suite 2100, Seattle, WA 98101,  
jallen@omwlaw.com, (206) 447-7000.

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 3:08-CV-05745-FDB

**PROOF OF SERVICE**

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This subpoena for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I served the subpoena by delivering a copy to the named individual as follows: \_\_\_\_\_

\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the subpoena unexecuted because: \_\_\_\_\_

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also  
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of  
\$ \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:



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**(e) Contempt.** The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

## **EXHIBIT 2**

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT TACOMA

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TODD and ANNE ERICKSON,  
individually and the marital  
community composed thereof,  
Plaintiffs,

-vs- Case No.  
C08-5745 FDB

MICROAIRE SURGICAL INSTRUMENTS,  
LLC, a Virginia limited liability  
company doing business in the  
State of Washington,  
Defendant.

\*\*\*\*\*

DEPOSITION OF JOHN PASCALOFF

9:59 a.m. to 2:11 p.m.

December 7, 2009

Ruckersville, Virginia

REPORTED BY: Kimberly A. Adderley, RMR

<p>2</p> <p>1 Deposition of JOHN PASCALOFF, taken and 2 transcribed on behalf of the Plaintiffs, by and 3 before Kimberly A. Adderley, RMR, Notary Public in 4 and for the Commonwealth of Virginia at large, 5 pursuant to Federal Rule of Civil Procedure 30(a) 6 and 30(b)(6), and by Notice to Take Deposition; 7 commencing at 9:59 a.m., December 7, 2009, at 8 the Best Western, Executive Conference Room, 9 5920 Seminole Trail, Ruckersville, Virginia.</p> <p>10</p> <p>11</p> <p>12</p> <p>13 APPEARANCES OF COUNSEL:</p> <p>14</p> <p>15</p> <p>16 HAGENS, BERMAN, SOBOL &amp; SHAPIRO, L.L.P. 17 1301 Fifth Avenue, Suite 2900 18 Seattle, Washington 98101 19 (206) 623-7292 20 tony@hbsslaw.com 21 BY: ANTHONY D. SHAPIRO, ESQUIRE 22 Counsel for the Plaintiffs 23 24 25</p>	<p>4</p> <p>1 INDEX 2 WITNESS: 3 JOHN PASCALOFF 4 Examination by Mr. Shapiro.....5 5 6 7</p> <p>8 EXHIBITS 9 NUMBER PAGE 10 1 - Second Amended Notice of Deposition 20 11 2 - Request for Production No. 16 63 12 3 - Request for Production No. 12 83 13 4 - Request for Production No. 20 90 14 5 - Defendant's Supplemental Response 100 to Plaintiff's First Request for Production of Documents 15 6 - Compilation of Documents 113 16 7 - Compilation of Documents 125 17 8 - Complaint Tracking 131 18 9 - Engineering Drawing 136 19 10 - Engineering Drawing 137 20 ***** 21 22 23 24 25</p>
<p>3</p> <p>1 APPEARANCES OF COUNSEL CONT'D: 2 3 4 OGDEN, MURPHY &amp; WALLACE, P.L.L.C. 5 1601 Fifth Avenue, Suite 2100 6 Seattle, Washington 98101-1686 7 (206) 447-7000 8 dyoshida@omwlaw.com 9 BY: D.K. YOSHIDA, M.D., J.D. 10 Counsel for the Defendants 11 12 13 COLSON ASSOCIATES, INC. 14 One North Franklin Street, Suite 2420 15 Chicago, Illinois 60606-3451 16 (312) 980-1100 17 brett.sarason@colsonassociates.com 18 BY: BRETT M. SARASON, ESQUIRE 19 Corporate Counsel 20 21 22 23 24 25</p>	<p>5</p> <p>1 (9:59 a.m., December 7, 2009) 2 3 4 5 JOHN PASCALOFF, 6 was sworn and testified as follows: 7 EXAMINATION 8 BY MR. SHAPIRO: 9 Q. Good morning, sir. 10 A. Good morning. 11 Q. Would you state your name and spell 12 your last name, please. 13 A. It is John, last name is Pascaloff, 14 P-A-S-C-A-L-O-F-F. 15 Q. And would you give us a business 16 address, please? 17 A. 1641 Edlich Drive, Charlottesville, 18 Virginia 22911. MicroAire Surgical Instruments, 19 LLC is the name of the company. 20 Q. And how long have you worked for 21 MicroAire Surgical Instruments -- 22 A. I came to -- 23 Q. -- LLC? 24 A. -- work for them April 1995. 25 Q. Okay. Let me just -- you and I just</p>

<p style="text-align: right;">138</p> <p>1 BY MR. SHAPIRO:</p> <p>2 Q. Take a look at Exhibit 10, sir. What</p> <p>3 is Exhibit 10?</p> <p>4 A. It's the exhaust muffler.</p> <p>5 Q. Okay. Now, this is a component drawing</p> <p>6 for the exhaust muffler for the Surgairtome Two?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Okay. And that, just so we are clear,</p> <p>9 Exhibit 10, this component drawing would relate to</p> <p>10 the muffler that we looked at, muffler part we</p> <p>11 looked at in Exhibit 9; correct?</p> <p>12 A. Yes, it does.</p> <p>13 Q. Now, Exhibit 10, this component drawing</p> <p>14 bears your signature; correct?</p> <p>15 A. It does.</p> <p>16 Q. Okay. You checked this drawing while</p> <p>17 you were at Hall Surgical; correct?</p> <p>18 A. I did.</p> <p>19 Q. Okay. And you signed off on the</p> <p>20 muffler exhaust drawing in 1980; correct?</p> <p>21 A. That's correct.</p> <p>22 Q. That was 12/17/1980?</p> <p>23 A. Yes, sir.</p> <p>24 Q. And that's your signature on the</p> <p>25 document?</p>	<p style="text-align: right;">140</p> <p>1 question there.</p> <p>2 MR. SHAPIRO: All right.</p> <p>3 BY MR. SHAPIRO:</p> <p>4 Q. And you had indicated earlier -- and</p> <p>5 this exhaust muffler, one of the purposes behind</p> <p>6 this exhaust muffler was to lessen noise; correct?</p> <p>7 A. Correct.</p> <p>8 MR. SHAPIRO: All right. I don't have</p> <p>9 anything further.</p> <p>10 MR. YOSHIDA: All right. Okay. We are</p> <p>11 done.</p> <p>12 We will reserve.</p> <p>13 MR. SHAPIRO: Okay.</p> <p>14</p> <p>15 (Deposition concluded at 2:11 p.m.)</p> <p>16</p> <p>17 (Signature reserved)</p> <p>18</p> <p>19 * * * * *</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">139</p> <p>1 A. Yes, sir.</p> <p>2 Q. And this appears to be a true and</p> <p>3 accurate copy of the component drawing for the</p> <p>4 exhaust muffler that you signed off on for the</p> <p>5 Surgairtome Two drill while you were at Hall?</p> <p>6 A. Yes, sir.</p> <p>7 Q. Okay. So, when you came to MicroAire,</p> <p>8 you were aware that Hall was utilizing an exhaust</p> <p>9 muffler in the drill that you've identified as the</p> <p>10 competitive counterpart to the 2910-100; correct?</p> <p>11 A. Well, that was 15 years before I came,</p> <p>12 and I had forgotten about that.</p> <p>13 Q. Okay. All right. But, as you look at</p> <p>14 these documents now?</p> <p>15 A. I can't argue it.</p> <p>16 Q. Okay. And that is your signature on</p> <p>17 the drawing; correct?</p> <p>18 A. It is.</p> <p>19 Q. Okay. Does that refresh your memory</p> <p>20 that Hall used an exhaust muffler in the</p> <p>21 Surgairtome Two prior to your moving from Hall --</p> <p>22 A. They did.</p> <p>23 Q. -- to MicroAire?</p> <p>24 A. They did.</p> <p>25 MR. YOSHIDA: Don't overlap his</p>	<p style="text-align: right;">141</p> <p>1 I certify that I have read or had read</p> <p>2 to me the foregoing transcript.</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9 JOHN PASCALOFF</p> <p>10</p> <p>11</p> <p>12</p> <p>13 COMMONWEALTH OF VIRGINIA to wit:</p> <p>14 Subscribed to and sworn before me</p> <p>15 this _____ day of _____ 2009.</p> <p>16 My commission expires:</p> <p>17 _____</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 Notary Public</p> <p>23 (AFFIX NOTARY SEAL)</p> <p>24</p> <p>25 REPORTED BY: Kimberly A. Adderley, RMR</p>

## **EXHIBIT 3**

---

To: Emily Grant

From: Dennis Foster

Date: March 17, 2010

Subject: Erickson v. MicroAire

Emily, following are my experience, observations and opinions regarding the historical and current industry designs of high-speed oral surgery power equipment as it relates to noise levels and the relative awareness of user harm regarding device noise levels.

Expertise: I began my tenure in the power surgical manufacturing industry in early 1977 with market leader in the industry Hall Surgical. The company was founded in the 1960's by a prominent oral surgeon and inventor Dr. Hall. Over the 18 years with Hall I served in many positions within the organization (see attached CV) from assembly supervisor, manufacturing engineering supervisor, service manager etc. During those years I spent much of it participating in the development of various powered surgical devices including being the primary engineering technician for the development of the Hall Surgairtome II pneumatic oral surgery handpiece.

After deciding to stay in California when Hall Surgical moved to Largo Florida in 1995, I started a business with two former Hall managers focusing on the repair and maintenance of nearly all manufacturers powered surgical and dental devices both domestically and internationally. During the following 9 years we reverse engineered most of the common pneumatic and electronic devices allowing our company (PyraMed) to be a high quality one stop repair facility for most of their repair needs in this specialized field.

From the inception of the company, PyraMed contracted our engineering expertise to several small and large medical device manufacturers as well s surgeons developing various medical devices primarily related to power equipment. As the company was able to finance its own product development, we created several of our own lines of power equipment one being for small bone procedures, another for large bone orthopedic procedures. One in particular was an oral surgical hand piece very much like the Hall Surgairtome Two.

**Regarding Decibel levels:** During the design phase of the Hall Surgairtome Two, the design engineer on the project (Hugh Yeoman's) consulted with oral surgeons that were considered champions in the field to elicit opinions regarding what improvements could be made to the current industry standard hand piece in the industry which was a similar sized device with a turbine style motor. The design evolved and was released to the field in the early 1980's basically in the same configuration, which it is today.

The only comment from those initial surgical consultants regarding noise was a request to try to reduce the pitch of the device, which was as I recall more a nuisance than a safety concern. Consequently the designer created and installed what was called a muffler to try to change the pitch of the device. In my many years of building and servicing this particular device, the muffler made little improvement in the overall noise reduction let alone any significant chance in the overall output pitch of the device.



During the early years at PyraMed servicing the Hall Surgairtome Two I became aware that Hall (Then Linvatec) had removed the muffler from the device. Because I was as familiar as anyone at Linvatec with the value of this muffler in this device, it's my opinion that it was removed because it was more of a problem for the users than of any real value for noise. By that I mean this component was the cause of many field failures as it would either move from its normal seated position and restrict the performance or cause the device to be inoperable or clog from debris overtime also causing performance problems.

In my 30 + years of experience, generally most all of the common or popular High speed oral surgical hand pieces in the field are very similar in their output noise decibel levels including but not limited to the MicroAire High Speed Drill, but very if anything in their pitch. But it is also true that a given product such as the Hall Surgairtome Two drill's pitch will vary from device to device due to various factors such as output speed.

As I had noted above, when Linvated removed the muffler they also inserted a restrictor in the intake of the device (a component which allows the assembly/service technician to regulate or adjust the speed of the device, which I believe was an attempt to affect the output pitch of the product.

From previous tests conducted over the years using decibel meters to assess changes in wear of a particular product or accessory or as an element of comparison of one manufactures product such as a cutter (bur or saw blade) to our product or a product under development or review, it is my experience that a decibel level of 85 to 90 dB at a distance of around 18 to 20" is very typical in both pneumatic as well as many electrical devices, especially the most common or popular devices currently in use.

In all of my years in the industry, especially servicing all the major brands in use over the years the only other time I recall anyone in the surgical arena complaining about or requesting the reduction of noise or even commenting about noise in a surgical device was during a design project that I consulted on with Medtronic Midas Rex. The Midas Rex high-speed pneumatic drill was, and I believe still is the market leader in neurological and skull based power equipment.

The neurosurgeons I worked with had a legitimate concern that because this high speed pneumatic device was commonly used continuously for many hours at a time for a given single surgery, that they were concerned of possible hearing loss even though most of these surgeons had used the predominant Midas drill (Classic family) for many years and no particular instance of hearing loss was identified or mentioned.

**OSHA and industry awareness of noise concerns:** In my years in the medical device industry, the issue of noise as a safety issue was never an area of concern when developing new or maintaining existing surgical devices. During the design phase of a surgical device all manufactures are required to create an FMEA (Failure Modes and Effects Analysis) and create a Risk analysis to assure a given product is safe and viable for its intended use. Federal guidelines such as OSHA indicate a time-weighted average that is far longer than any typical surgical approach or procedure at the decibel levels these types of devices produce, especially for oral surgery.



In my years working for medical device manufacturers as well as an independent third party repair provider which requires the review of the OEM (original Equipment Manufacturer) documentation to assess the published nominal performance attributes, I have no knowledge of any manufacturers literature that warns of noise or the potential of hearing loss.

**Regarding other devices that incorporate muffler type devices:** There are a few surgical devices that I am aware of that contain a means of effecting the output sound of the device. Besides the Hall Surgairtome Two drill there are several high-speed neurological devices that have components or media within the supply hose intended to affect the sound output. They are the Anspach, Midas Rex and Komet/Brasseler devices. Again these are hand pieces that are used for many hours of continuous use during a given surgical procedure. And in my experience working with these devices they are in the same relative output decibel level as the oral surgical devices, which mostly differ, as do the oral surgical hand pieces in the pitch they produce in use.

**Medical device manufacturers acceptance test parameters:** Although I have not been privy to all medical device manufacturers test parameters that specify what performance and attribute specifications their power equipment must pass, I have seen the Hall/Linvatec, Medtronic Midas Rex, Komet Medical, Brasseler/Tava, MicroAire, AltAir, Sodem, and Desoutter Medical test parameters and none of these devices are tested for noise (except comments asking the inspector to observe for unusual noise).

**Final note:** Working in this field for approximately 33 years I have been proud to work with so many professionals who strive to produce safe and effective medical devices knowing they can be used on our loved ones or us. And I can tell you from personnel experience those professionals participating in the development process seriously challenge any possible potential of a safety concern to assure even user error can be mitigated if at all possible of feasible.

Further, the federal regulations for this industry mandate that any legitimate complaint from the field must be documented by regulatory personnel, addressed and reported to the federal government especially if an injury or realistic potential safety concern is communicated by not only the users, but any employee of a medical device manufacturer. And if over all the years these types of devices were to have caused injury due to noise levels all manufactures would be required to mitigate this concern even if it were simply to include warnings in the device instructions for use.

For my services as a professional witness in this matter I have asked for \$200.00 per hour for time spent providing expert services, including reimbursement of reasonable expences and \$100.00 per hour for all travel time.

Due to the fact that discovery is ongoing in the case of Erickson v. MicroAire, I reserve the right to supplement my reports.